

REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claim status and amendments

Claims 1-40 currently are pending.

Claim 2 has been canceled. Claim 2 has now been incorporated into claims 1 and 21. In light of the cancellation of claim 2, the dependent claim 24 has also been canceled

Claims 1, 4-5, 10-11, 19-22, and 25 currently are being amended. Claim 1 has been amended to remove the phrase “sufficient.” Claim 1 has also been amended to remove a typographical error. Further, claim 1 and 21 have been amended to include the phrase “where the composition has a high viscosity at low shear conditions as defined by a viscosity of greater than about 25,000 cP at 37°C at a shear rate of 0.24 s^{-1} and a viscosity of less than about 5000 cP at 37°C when a shear rate of at least about 100 s^{-1} is applied.” Claims 4 and 5 have been amended to correct the claim dependency in light of the cancellation of claim 2. Claims 10-11 and 19-22 have been amended to include the phrase “copolymer” to ethylene vinyl alcohol. Claims 21 and 22 have also been amended to include the phrase “weight/final weight” or “/final weight” in response to the rejection under 35 U.S.C. §112. Claim 25 has been amended to correct the claim dependency in light of the cancellation of claim 24. No new matter has been added by these amendment. Applicants request entry of these amendments.

Support for these amendment can be found in the application as originally filed. For example, the support for the phrase “where the composition has a high viscosity at low shear conditions as defined by a viscosity of greater than about 25,000 cP at 37°C at a shear rate of 0.24 s^{-1} and a viscosity of less than about 5000 cP at 37°C when a shear rate of at least about 100 s^{-1} is applied” in claim 1 and 21 can be found in claim 2 as originally filed and now canceled. The support for the phrase “copolymer” can be found on page 17, paragraph [00081]; and

support for the phrase “weight/final weight” can be found on page 25, paragraph [000118] and page 26 paragraph [000124].

The cancellation of the subject matter is not intended to be the dedication of the canceled subject matter to the public. Applicants reserve the right to file one or more continuation applications on the canceled subject matter.

Claims 23 and 25-29 are withdrawn as being drawn to non-elected invention.

Claims 1, 3-22 and 30-40 currently are under consideration.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

Election/restriction

Applicants thank the Office for acknowledging the election with traverse of Group I, claims 1-22 and 30-40. Applicants also thank the Office for acknowledging the election of species, ethylene vinyl alcohol, dimethylsulfoxide, and tantalum.

Claim Rejection under 35 U.S.C. §112

Claims 1, 10-11, 20-21 and 22 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicants regards as the invention.

A. The Office states that the term “sufficient” in claim 1 is allegedly indefinite. *See* page 3 of the Office Action.

In order to expedite prosecution, Applicants have removed the term “sufficient” from claim 1. Withdrawal of this rejection is respectfully requested.

B. The Office states that the claims 10-11, 20-21 and 22 are allegedly indefinite since ethylene vinyl alcohol is a copolymer and not just "ethylene vinyl alcohol." *See* page 3 of the Office Action.

In order to expedite prosecution, Applicants have added the phrase "copolymer" to the claims. Withdrawal of this rejection is respectfully requested.

C. The Office has required clarification regarding the weight % in claims 21 and 22. *See* page 3 of the Office Action.

Applicants have added the phrase "weight/final weight" to provide further clarification. Withdrawal of this rejection is respectfully requested.

In view of above, Applicants respectfully request withdrawal of this rejection under 35 U.S.C. §112.

Claim Rejection under 35 U.S.C. §102(e)

A. Claims 1-16, 18-23, 30-36, and 38-40 stand rejected under 35 U.S.C. §102(e), as being anticipated by Porter et al. (US 2004/0156781). The Office states that Porter et al. describes a polymer, a contrast agent, a solvent and a rheological modifier and that since the compositions have the same ingredients and the same concentrations it is inherent that the same composition will have the same properties such as viscosity. *See* pages 4-5 of the Office Action. Applicants traverse the rejection as follows.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Applicants contend that Porter et al. do not define the combination of all the essential parameters of the claimed invention, i.e., the shear rate, the viscosity, and the shear thinning index to achieve the delivery of a high viscosity embolizing composition. For example, Porter et

al. recite that, “the viscosity under static conditions should be at least 1.5 times over the dynamic viscosity.” *See* page 5, paragraph [0072] of Porter et al. Even though Porter et al. disclose a shear thinning index of at least 1.5, they do not define the dynamic shear rate as is defined in instant claims. The instant claims disclose a shear thinning index of at least 4 and define the shear rate to achieve that shear thinning index.

Further, the instant amended claims recite a composition defined by a viscosity of greater than about 25,000 cP at 37°C at a shear rate of 0.24 s^{-1} and a viscosity of less than about 5000 cP at 37°C when a shear rate of at least about 100 s^{-1} is applied. This composition describes at least 5 times decrease in the viscosity of the composition as the shear rate is increased. This shear thinning index of at least 5 is not recited anywhere in Porter et al. Additionally, Porter et al. do not define the combination of the viscosity achieved by a particular shear rate. Porter et al. describe, in Table I on page 8, a change in the viscosity of the composition with a change in the shear rate where 0.93 s^{-1} of the shear rate results in the viscosity of 450 cP and 93 s^{-1} of the shear rate results in the viscosity of 209 cP. There is a shear thinning index of only 2.15 ($450\text{cP}/209\text{cP}$) in Porter et al. which is far from a shear thinning index of at least 4 as in instant amended claims. Additionally, the low shear viscosity (9,000cP) in Porter et al. (*see* Figure 1 of Porter et al.) is significantly below the requirement of $>25,000\text{cP}$ as in instant amended claims. Therefore, Porter et al. does not describe all the claim elements either expressly or inherently. Applicants respectfully request withdrawal of this rejection under 35 U.S.C. § 102(e) for claims 1-16, 18-23, 30-36, and 38-40.

B. Claims 1-4, 8-9, 12-15, 30-33, and 36-39 stand rejected under 35 U.S.C. §102(e), as being anticipated by Porter (US 2003/0194389). The Office states that Porter describes a poly(2-cyanoacrylate), a visualization agent, a suitable carrier, and a rheological modifier. *See* page 5 of the Office Action. Applicants traverse the rejection as follows.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Applicants contend that the composition of Porter is different from the composition of the instant claimed invention. Porter describes an occlusive composition comprising a dual cyanoacrylate monomer and a visualizing agent. Therefore, composition consists of reactable monomer compositions (*see* page 1, paragraph [0011] and paragraph [0012] of Porter) which are present in a suitable carrier. This is in sharp contrast to the instant claimed invention where the composition contains a biocompatible polymer (not a monomer or a prepolymer) dissolved in a biocompatible solvent (not a carrier agent) for solid, precipitate formation. This is further evident by the fact that the Office has not included claims 10-11 in this rejection which are related to a biocompatible polymer. Further, Porter fails to disclose any viscosity values, shear rates or shear indices, which are critical to the instantly claimed invention.

In the absence of all the claim elements described either expressly or inherently in Porter, withdrawal of this rejection under 35 U.S.C. §102(e) for claims 1-4, 8-9, 12-15, 30-33, and 36-39 is respectfully requested.

Claim Rejection under 35 U.S.C. §103(a)

Claims 1-22 and 30-40 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Greff et al. (WO 00/71170) in view of Porter (US 2003/0039696). The Office states that it would have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to combine the art since Greff discloses embolic compositions except for rheological modifiers and Porter discloses the use of rheological agents. *See* pages 6-8 of the Office Action.

Applicants traverse the rejection for the following reasons.

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable

expectation of success must both be found in the prior art, not in applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Applicants respectfully state that the Office Action fails to present a *prima facie* case of obviousness. The cited references do not teach or suggest all the claim limitations. Porter states that the rheological modifier can impart apparent viscosities of between 25 cP and 2000 cP to the composition (page 2, paragraph [0014] in Porter). However, since Porter does not disclose shear rates, the viscosity is a Newtonian viscosity (shear rate independent). Meanwhile, the compositions of the claimed invention are non-Newtonian or thixotropic, and work by shear thinning to allow for ease and control of the injection and for site-specific embolus placement. Porter although mentions shear thinning (page 5, paragraph [0049]), there is no disclosure of viscosities, shear rates or shear indices that are critical elements of the claimed invention. In particular, Porter et al. does not disclose a shear thinning index of at least 4 as in instant claimed invention. Therefore, the cited references neither alone nor in combination teach or suggest all the claim elements.

Further, the cited references provide no suggestion or motivation to a person of skill in the art to modify and combine the references to achieve the viscosities, shear rates, and shear indices of the claimed invention. There is no reasonable expectation to a person of skill in the art to combine the references and come up with the claimed invention.

In view of the absence of all the claim limitations in the cited references, Applicants respectfully request the withdrawal of this rejection under 35 U.S.C. §103(a).

Provisional obviousness type double patenting rejection

Claims 1-4, and 8-9 are rejected on the ground of provisional nonstatutory obviousness-type double patenting as being unpatentable over claims 7-16 and 20 of co-pending application no. 10/789,946. *See* page 9 of the Office Action.

CONCLUSION

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Please direct all correspondence to the undersigned attorney or agent at the address indicated below.

Respectfully submitted,

Date

08/27/07

By



FOLEY & LARDNER LLP
Customer Number: 38706
Telephone: (650) 251-1139
Facsimile: (650) 856-3710

Vandana Bansal
Patent Agent
Registration No. 54,979